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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,887	01/05/2004	Ching-Hsiang Hsu	001409.00008	2087
22907	7590	01/22/2007	EXAMINER	
BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001			BAGGOT, BRENDAN O	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	01/22/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/750,887	HSU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brendan O. Baggot	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10/1306.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 and 20-34 is/are pending in the application.  
 4a) Of the above claim(s) 29-34, 35-39 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-18 and 20-34 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. The Office acknowledges the receipt of Applicant's paper, filed 10/13/06

Claims 1-18, 20-39 are pending. Claims 29-34 are withdrawn. Claim 19 is cancelled.

Claims 35-39 are newly added, are drawn to non-elected inventions and are withdrawn from consideration per Applicant's election of ZYMV. Claims 1-28 is/are examined in the instant application. This restriction is made FINAL.

2. All prior rejections not repeated here are withdrawn.

#### ***Claim Rejections - 35 U.S.C. §103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4, 7-18, 21-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mason, et al (PG PUB 0079248 A1, 4/03) and further in view of Hsu et al (International Immunology, 8:1405-1411, 1996). Mason teaches a process for producing a protein comprising the steps of: (a) constructing a plant transformation vector that comprises a DNA sequence operably linked to a plant-specific promoter, transforming a plant cell with the vector, and obtaining the protein from the plant cell (pp. 1-83). Mason further teaches an edible protein (parag. 222), modified plant virus vector (See the title, abstract, and parags 287, 288, 296, 365 for example), an ER

signal peptide (parag. 47), a 35s promoter (parag. 47), a selectable marker (parag. 109), a process for producing an antigenic composition (See parag. 387 for example), and a potato (parag. 103). Mason does not teach dust mite allergen Der p 5. Hsu teaches dust mite allergen, Der p 5 cDNA, expression of Der p 5, and Der p 5 protein (See the abstract; p. 1406, 3<sup>rd</sup> parag.; p. 1406, 5<sup>th</sup> parag., right hand side) and that dust mite allergen causes disease affecting 20% of the population and is an important cause of morbidity and mortality (Hsu, p. 1405).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the Der p 5 cDNA taught by Hsu for the BeYDV (for example) protein taught by Mason for the purposes of expressing Der P 5 in potato or other edible plant or plant portion to create an edible therapeutic agent. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

Applicant traverses primarily that one skilled in the art would not have had a reasonable expectation of success because not all foreign proteins are efficiently produced in plants. Applicants cites references teaching that some plant vacuoles of leaves are of the lytic type and that some foreign protein [with certain vacuolar targeting signals not listed in the instant Claims] expression targeted to the leaves can enter leaf vacuoles of the lytic type, and that leaf vacuoles can degrade proteins [which are targeted there] (See Applicant's response filed 13 October 2006, page 11-12).

Applicant's arguments filed 10/13/06 have been fully considered but they are not persuasive. Applicant's arguments are not commensurate in scope with the claims.

Applicant's claims do not contain any limitations addressing any of the problems which applicant cites: namely protein prediction, protein degradation, and/or protein sorting. The claims are directed to simple protein expression which is anticipated by the prior art. Accordingly, the rejection is maintained.

5. Claims 1-3, 5-17, 19-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al (Bot. Bull. Acad. Sin. 43: 261-268, 2002) and further in view of Hsu et al (International Immunology, 8:1405-1411, 1996). Lin teaches a ZYMV based system for expressing foreign proteins in cucurbits. ZYMV as a vector to express foreign proteins of interest. (p. 267, last para.) Lin does not teach Der p 5. Hsu teaches dust mite allergen, Der p 5 cDNA, expression of Der p 5, and Der p 5 protein (See the abstract; p. 1406, 3<sup>rd</sup> parag.; p. 1406, 5<sup>th</sup> parag., right hand side) and that dust mite allergen causes disease affecting 20% of the population and is an important cause of morbidity and mortality (Hsu, p. 1405). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made substitute the Der p 5 protein of Hsu for the generic foreign protein in the ZYMV vector expression system of Lin for the purpose of expressing Der p 5 in cucurbits such as *Cucurbita pepo* L. var. Zucchini to create an edible therapeutic agent. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

Applicant traverses primarily that "...successful production of a foreign protein in plants was not predictable as of the effective filing date", "expression a (sic) foreign protein in a transgenic plant requires empirical determination", "expression of a dust

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mite allergen in a mammal is not predictive of successful expression in a plant", and that expression of "each individual protein requires empirical determination", and that if "a recombinant protein contains a cryptic vacuolar sorting signal, it can be fatally targeted to a plant vacuole where it is degraded. (See Applicant's response filed 13 October 2006, page 12-13).

Applicant's arguments filed 10/13/06 have been fully considered but they are not persuasive. Applicant's arguments are not commensurate in scope with the claims. See response to Applicant's arguments hereinabove. Applicant's claims do not contain any limitations addressing any of the problems which applicant cites: namely protein prediction, protein degradation, and/or protein sorting. The claims are directed to simple protein expression which is anticipated by the prior art. Accordingly, the rejection is maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

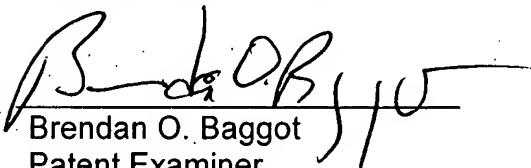
**Remarks**

7. No claim is allowed.

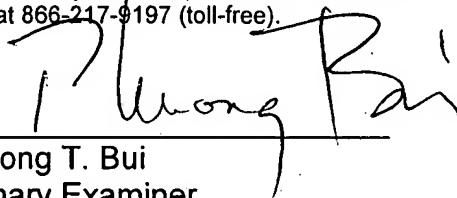
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brendan O. Baggot  
Patent Examiner  
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Phuong T. Bui  
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